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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/892,403 | 07/10/97 | MURPHY | 17034-100000 |

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| EXAMINER |
|--------------|
| BRUMBAUGH, D |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1015 | |

DATE MAILED: 12/10/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/892,403

Applicant(s)
Murphy et al.

Examiner
Brenda Brumback

Group Art Unit
1815



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-62 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-62 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 2-10, drawn to recombinant respiratory syncytial viruses (RSV) with temperature sensitive amino acid substitutions and methods of making recombinant RSV, classified in class 424, subclass 199.1 and to claims 1, 47-51, and 61 to the extent that they read on claims 2-10.
 - II. Claims 13, 14, 27, 28, 52, and 53 drawn to recombinant RSV with a modified SH gene, classified in class 424, subclass 199.1 and to claims 1, 11, 12, 26, and 47-51 to the extent that they read on claims 13, 14, 27, 28, 52, and 53.
 - III. Claims 20, 31-34, 54, 56-58, and 62 drawn to recombinant RSV with heterologous RSV genes, classified in class 424, subclass 199.1 and to claims 1, 11, 47-51, and 61 to the extent that they read on claims 20, 31-34, 54, 56-58, and 62.
 - IV. Claims 21, 35, and 59 drawn to recombinant RSV with genome modifications to encode non-RSV proteins, classified in class 424, subclass 199.1 and to claims 1, 26, and 47-51 to the extent that they read on claims 21, 35, and 59.

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- V. Claim 19, drawn to recombinant RSV with a nucleotide modification in a translational start codon, classified in class 424, subclass 199.1 and to claims 1 and 11 to the extent that they read on claim 19.
- VI. Claims 18 and 38, drawn to recombinant RSV with a nucleotide modification in a termination codon or a GS or GE transcription signal, classified in class 424, subclass 199.1 and to claims 1 and 11 to the extent that they read on claims 18 and 38.
- VII. Claims 22-25, 36, 37, and 60, drawn to recombinant RSV with a parainfluenza (PIV) gene classified in class 424, subclass 199.1 and to claims 1, 11, 30, 47-51, 54, and 55 to the extent that they read on claims 22-25, 30, 36, 37, and 60.
- VIII. Claims 15-17, 29, 30, and 54 drawn to recombinant RSV with a nucleotide modification to a cis-acting regulatory sequence classified in class 424, subclass 199.1 and to claims 1, 11, 30, 47-51, and 55 to the extent that they read on claims 15-17, 29, 30, and 54.
- IX. Claims 39-46, drawn to a vaccine and methods of stimulating the immune system, classified in class 199.1, subclass 199.1 and to claims 26 and 38 to the extent that they read on claims 39-46.

2. Inventions I-VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the

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particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each of the subcombination groups is drawn to recombinant RSV with different and distinct mutations. The subcombinations have separate utilities in vaccine production, diagnostics, and research applications.

3. Inventions I-VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant RSV of groups I-IX can be used in diagnostics, as well as for vaccines; and vaccines can also be made with non-recombinant attenuated RSV strains.

4. Because these inventions are distinct for the reasons given above and each of the groups requires a separate search, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Primary Examiner Michael Woodward whose telephone number is (703) 308-3890 or Supervisory Patent Examiner Marian Knode whose telephone number is (703) 308-4311. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1815 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1815 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday,

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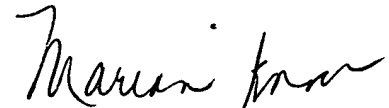
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Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback

November 13, 1997

A handwritten signature in cursive script, appearing to read "Marianne Knode".

MARIANNE KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800